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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,677	02/05/2001	Jan Otto Solem	JM-050 CIP	3473
7590 12/27/2005			EXAMINER	
CHRIS JAMES EDWARDS LIFESCIENCES LLC ONE EDWARDS WAY IRVINE, CA 92614			CHATTOPADHYAY, URMI	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 12/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/775,677

Applicant(s)

SOLEM ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-17, 22, 25-27, 30, 32-40, 74 and 86-89 is/are pending in the application.
- 4a) Of the above claim(s) 25-27, 32-36, 74 and 89 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-17 is/are allowed.
- 6) ☒ Claim(s) 22, 30, 37-40 and 86-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Request for Continued Examination

1. The request filed on 12/9/05 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 09/775,677 is acceptable and a RCE has been established. An action on the RCE follows.

Response to Amendment

2. The amendment filed 12/9/05 has been entered. Claims 75-85 have been canceled, and new claims 86-89 have been added. Claims 14-17, 22, 25-27, 30, 32-40, 74 and 86-89 are currently pending, of which claims 25-27, 32-36 and 74 remain withdrawn from consideration for being drawn to non-elected species. New claim 89 is also withdrawn because it is directed to non-elected Species 1 (Figures 8 and 9) and Species 2 (Figures 10 and 11). Applicant had elected Species 9 (Figures 19 and 20) in the paper filed 8/6/02, and the elected embodiment does not include an elongate body that is "*biased to the second shape*" (italicized for emphasis). The claims being considered for further examination on the merits are claims 14-17, 22, 30, 37-40 and 86-88.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 40 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 40 recites the limitation "the vessel" in lines 3 and 8-9. There is insufficient antecedent basis for this limitation in the claim. It appears that "the vessel" should be changed to --the body space--, and will so be interpreted for examination purposes.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 22, 30, 37-40 and 86-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Imran (USPN 5,817,126, as cited in applicant's IDS) in view of Orth et al. (USPN 5,591,197, as cited in last office action).

Imran discloses a medical device and medical system for remodeling an extravascular tissue structure adjacent to a vessel/body space in a patient and an apparatus with all the elements of claims 22, 38 and 40, but is silent to the elongate body being adapted to be fixed to the vessel/body space and to exert a force from within the coronary sinus onto the mitral valve annulus in order to remodel the mitral valve annulus. See Figure 1 for a medical device (10) comprising an elongate body (11) extending between a proximal end (24) and a distal end (44), and that is adjustable from a first configuration having a first shape such that the elongate body is

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adapted to be delivered at least in part into the vessel/body space to a second configuration having a second shape (column 1, lines 18-24). See column 3, lines 26-43 for the dimensions of the elongate body (11) being within ranges that would allow for it to be inserted into and positioned in the first configuration at least in part within a coronary sinus. See Figure 1 for the distal end (44) of the elongate body (11) being spaced distally from the proximal end (24) of the elongate body (11) in the first and second configurations. See columns 6-7, lines 58-3 for a deployment system cooperating with the elongate body (11) and being adapted to and capable of at least in part delivering the elongate body (11) in the first configuration to the coronary sinus. See Figure 1 and columns 3-4, lines 63-1 for the elongate body (11) having two first segments (20, 40) and a second segment (60) disposed between the first segments (20, 40). See column 6, lines 35-37 for the second segment (60) being capable of decreasing its axial length to draw one of the first segments towards the other first segment.

Orth et al. teaches a stent (10) that forms barbs upon expansion for contacting and penetrating the vessel wall in order to anchor and affix the stent thereto. See column 1, lines 8-9, column 3, lines 33-35 and column 7, lines 45-47. It would have been obvious of one of ordinary skill in the art to look to the teachings of Orth et al. to modify the elongate body (11) of Imran by having the two first segments (20, 40) be barb forming stents in order for the barbs to contact and penetrate the vessel wall. This will anchor and affix the stent to the vessel wall and prevent migration of the stent. The elongate body is adapted to adjust to the second configuration after it is fixed to the coronary sinus in the following manner: when the first segments (20, 40) are expanded and affixed to the coronary sinus wall, subsequent expansion of the second segment (60) will reduce a longitudinal length of a portion of the coronary sinus by drawing one of the

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first segments attached to a first portion of the coronary sinus towards the other first segment attached to a second portion of the coronary sinus. See column 5, lines 62-65. This will cause the elongate body (11), which is fixed to the coronary sinus, to exert a force from within the coronary sinus onto the mitral valve annulus and remodel the mitral valve annulus without fully encircling the mitral valve annulus (claim 86).

Claim 30, see column 2, lines 30-32 for the flexibility of the second segment (60) permitting the elongate body (11) to follow the shape of the coronary sinus, and thereby define an arc shape in the second configuration.

Claim 37, see rejection to claim 22, supra. By drawing one of the first segments attached to a first portion of the coronary sinus towards the other first segment attached to a second portion of the coronary sinus by expanding the second segment (60), the elongate body (10) will compress the mitral valve annulus to thereby reduce the diameter of the space.

Claim 39, see columns 6-7, lines 58-3 for the deployment system comprising a delivery member (catheter) coupled to the elongate body (11) and adapted to and capable of advancing the elongate body (11) into the coronary sinus.

Claim 87, see column 3, lines 54-56 for the elongate body comprising a memory material (nitinol).

Claim 88, see rejection to claim 22, supra. By modifying the elongate body (11) of Imran by making the two first segments (20, 40) barb forming stents, the barbs of the segments will contact and penetrate the vessel wall upon expansion to prevent migration thereof. The two first segments (20, 40) are the proximal and distal ends of the elongate body (11).

Allowable Subject Matter

7. Claims 14-17 are allowed.

Response to Arguments

8. Applicant's arguments filed 12/9/05 have been fully considered but they are not persuasive. In response to applicant's argument that neither Imran nor Orth teach or suggest that the stent is adapted "after it is fixed to the coronary sinus" to remodel a mitral valve annulus adjacent to the coronary sinus, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Imran discloses in column 3, lines 26-43 the dimensions of the stent as being within ranges that would allow for it to be inserted into and positioned in the first configuration at least in part within a coronary sinus. Therefore, although Imran does not disclose use of the stent within the coronary sinus, the stent is structurally capable of being used therein. Imran also discloses in column 6, lines 22-39 that the three segments (first segments 20, 40 and second segment 60) of the stent are separately made and then assembled together. The segments are assembled in such a manner that they are structurally capable of independent expansion. Applicant has not provided evidence to prove otherwise. While Imran does disclose the deployment of the full stent in one step, the stent is structurally capable of being deployed in other fashions, specifically expansion of first segments (20, 40) followed by subsequent expansion of second segment (60). It is not required for product claims 22, 38 and 40 that the prior art disclose the method of expansion of the stent being in this

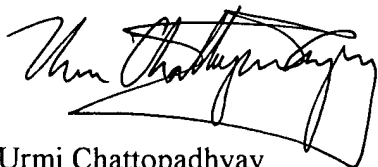
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specific fashion. Because the stent of Imran is *capable of* being expanded in this fashion, the limitation is met. When the stent of Imran is modified according to the teachings of Orth and expanded in the specified fashion, the change in length of the stent will occur *after* first segments (20, 40) are fixed in place by the barbs and during expansion of the second segment (60).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached Monday through Thursday and every other Friday from 9:00am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Urmi Chattopadhyay
Art Unit 3738



David J. Isabella
Primary Examiner